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09/936,565	02/04/2002	John J. Sauk	UNIMD 4	7145

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EXAMINER

YAEN, CHRISTOPHER H

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1643

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05/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Re: SAUK, JOHN J.

The amendment filed 2/20/2007 is acknowledged and entered into the record. Accordingly, claims 20-23 and 27-28 are canceled without prejudice or disclaimer.

Claims 1-19, 24-26, and 29-38 are pending, claims 1-19 are withdrawn from further consideration as being drawn to a non-elected invention.

Claims 24-26 and 29-38 are examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

The rejection of claims 24-26, 29-33, and 35-38 under 35 USC § 112, 1st paragraph for lacking adequate written support is maintained for the reasons of record. Applicant argues that the instant application has adequate written support for the claimed invention. Specifically, applicant contends the instant specification provides detailed structural features of the claimed peptides as well as methods routine methods for obtaining the claimed genus of peptides. Applicant further asserts that the specification provides guidance to those of skill in the art to test for the claimed peptides. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The standard for written description is not whether one of skill in the art could use routine methods in the art to obtain the claimed genus of peptides, rather the standard

is whether the specification at the time of the invention showed those of skill in the art that the applicant possessed the claimed invention. Moreover, the recitation of a general motif which provides multiple variable for amino acids does not give those of skill in the art a reasonable estimation that the application was in possession of the various peptides encompassed by the claimed invention.

Applicant further asserts that all members of the genus need not be disclosed in the specification because in the instant case the claimed peptide sequences is a motif with variables in which any one of twenty amino acids could be substituted into the chemical structure. Applicant further contends that those of skill could easily screen for the peptides by using the methods outlined in the specification wherein a peptide that binds to and modulates hsp47 is a peptide encompassed by the motif. Applicant's arguments have been carefully considered but are not found persuasive to overcome the rejection of record.

In deciding *The Regents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 (CAFC 1997), the Federal Circuit held that a generic statement that defines a genus of nucleic acids *by only their functional activity* does not provide an adequate written description of the genus. By analogy, a generic statement that defines a genus of protein binding molecules by only their common ability to bind the polypeptide of SEQ ID NO: 1 does not serve to adequately describe the genus as whole. The Court indicated that while applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a precise definition of a representative number of members of the genus, such as by reciting the

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structure, formula, chemical name, or physical properties of those members, rather than by merely reciting a wish for, or even a plan for obtaining a genus of molecules having a particular functional property. The recitation of a functional property alone, which must be shared by the members of the genus, is merely descriptive of what the members of genus must be capable of doing, not of the substance and structure of the members.

"[G]eneralized language may not suffice if it does not convey the detailed identity of an invention." *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004). Furthermore, the Federal Circuit has decided that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See *Noelle v. Lederman*, 69 USPQ2d 1508 1514 (CA FC 2004) (citing *Enzo Biochem II*, 323 F.3d at 965; *Regents*, 119 F.3d at 1568). In this instance, as in that, there is no language that adequately describes with the requisite degree of particularity necessary to satisfy the written description requirement the genus of structurally variable polypeptides because there are 7 positions represented by "X" which can be any one of twenty amino acids and 5 positions represented by "Hy" which can be any one of W, L, or F. Those of skill in the art cannot adequately assess possession of a peptide by the generalized function of binding as indicated, because HSP are chaperone proteins which are capable of binding to large number of peptides. Again, a description of what a material does, rather than of what it is, does not suffice to describe the claimed invention.

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Therefore, the rejection of claims under 35 USC 112, 1st paragraph is maintained for the reasons of record.

NEW REJECTIONS

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-26,29, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Vankann *et al* (J. Colloid and Interface Science 1996;178(1):241-250). Vankann *et al* teach a peptide that falls within the scope of the claimed peptide motif of SEQ. ID No: 1. (see exhibit A). Although the reference does not specifically teach that the purified peptide is capable of binding to and or modulating HSP47, the claims are drawn to the product *per se* and inherently, such a polypeptide would bind to and or modulate as claimed. Thus, the claimed peptide appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable

differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER H. YAEN
PRIMARY EXAMINER

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April 18, 2007